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| APPLICATION NO.                  | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|----------------------------------|-------------|----------------------|---------------------|------------------|
| 10/647,156                       | 08/22/2003  | Dirk Stenkamp        | 1/1387              | 1272             |
| 28501                            | 7590        | 04/30/2007           | EXAMINER            |                  |
| MICHAEL P. MORRIS                |             |                      | TRUONG, TAMTHOM NGO |                  |
| BOEHRINGER INGELHEIM CORPORATION |             |                      |                     |                  |
| 900 RIDGEBURY ROAD               |             |                      |                     |                  |
| P. O. BOX 368                    |             |                      | ART UNIT            | PAPER NUMBER     |
| RIDGEFIELD, CT 06877-0368        |             |                      | 1624                |                  |
| MAIL DATE                        |             | DELIVERY MODE        |                     |                  |
| 04/30/2007                       |             | PAPER                |                     |                  |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

|                              |                        |                     |  |
|------------------------------|------------------------|---------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b> | <b>Applicant(s)</b> |  |
|                              | 10/647,156             | STENKAMP ET AL.     |  |
|                              | <b>Examiner</b>        | <b>Art Unit</b>     |  |
|                              | Tamthom N. Truong      | 1624                |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) Responsive to communication(s) filed on 10 January 2007.
- 2a) This action is FINAL.                                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) Claim(s) 45-73 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) \_\_\_\_\_ is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) 45-73 are subject to restriction and/or election requirement.

**Application Papers**

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:
  1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO/SB/08)  
 Paper No(s)/Mail Date \_\_\_\_\_
- 4) Interview Summary (PTO-413)  
 Paper No(s)/Mail Date. \_\_\_\_\_
- 5) Notice of Informal Patent Application
- 6) Other: \_\_\_\_\_

***Election/Restrictions***

Applicant's amendment of 1-10-07 has cancelled claims 1-44, and added claims 45-73.

The cancelled claims has rendered moot the previous rejections and objection.

New claims 45-73 are directed to the subject matter of the elected Group I (formula I-1).

However, in view of the divergent subject matter and species of formula I-1, Group I is further restricted as below:

**Group I-a.** Claims 45-68 (in part), drawn to compounds of formula I-1 wherein both U and V are CH; pharmaceutical composition thereof, classified in classes 540, 544, 546, 548, 560, etc., various subclasses. Election of species is required if this group is elected.

**Group I-b.** Claims 45-68 (in part), drawn to compounds of formula I-1 wherein one U and V is N, and the other is CH; pharmaceutical composition thereof, classified in classes 540, 544, and 546, etc., various subclasses. Election of species is required if this group is elected.

**Group I-c.** Claims 45-68 (in part), drawn to compounds of formula I-1 wherein both U and V are N; pharmaceutical composition thereof, classified in classes 540, 544, 546, 548, 560, etc., various subclasses. Election of species is required if this group is elected.

**Group I-d.** Claims 69-72 (in part), drawn to multiple methods of uses; classified in classes 514, 540, 544, 546, 548, 560, etc., various subclasses. Further restriction to a compound group and election of species is required if this group is elected.

**Group I-e.** Claim 73 (in part), drawn to a complex pharmaceutical composition comprising a compound of formula I-1 and another active substance; classified in classes 514,

540, 544, 546, 548, 560, etc., various subclasses. Further restriction to a compound group and election of species is required if this group is elected.

The inventions of Groups I-a to I-c are drawn to compounds of different cores as U and V vary. Thus, formula I-1 is an improper Markush group. A reference reading on compounds of one group would not read on those of the other groups.

Inventions Groups [Ia – Ic] and Id are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, more than one use exists as evident by the many being claimed directed to whole classes of disorders.

The examiner has required restriction between product and method claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn method claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Method claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.**

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined method claims will be withdrawn, and the rejoined method claims **will be fully examined for patentability in accordance with 37 CFR 1.104**. Thus, to be allowable, **the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112**. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and method claims may be maintained. Withdrawn method claims that are not commensurate in scope with an allowed product claim will not be rejoined. See “Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b),” 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the method claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Groups I-e is independent and distinct from Ia – Ic since the simple compositions may be old or obvious while the complex combination of ingredients in Ie may be patentable due to superior or new properties (synergistic effects) not present in the single, active ingredient of Ia – Ic. Within group Ie, there is more than one invention as the claims recite multiple combinations

which require independent searches and separate consideration for compliance with 35 U.S.C 112.

Because these inventions are independent or distinct for the reasons given above and have acquired a separate status in the art in view of their divergent subject matter, restriction for examination purposes as indicated is proper.

Therefore, it would impose an undue burden on the Examiner and the Patent Office's resources to examine the instant application if unrestricted.

The above groups themselves are inclusive of patentably distinct subject matter. Accordingly, along with the election of one of the above groups, the following action is also taken.

Claim 45 is generic to the following disclosed patentably distinct species:

- 1) species having  $R^1R^2-N-X$  as 4-pyrrolidin-1-ylmethyl (e.g., 1<sup>st</sup> species in claim 60);
- 2) species having  $R^1R^2-N-X$  as 4-diethylamino-methyl (e.g., the 2<sup>nd</sup> species in claim 60);
- 3) species having  $R^1R^2-N-X$  as 4-piperidin-1-ylmethyl (e.g., the 3<sup>rd</sup> species in claim 60);
- 4) species having  $R^1R^2-N-X$  as 4-piperidin-1-ylmethyl (e.g., the 3<sup>rd</sup> species in claim 60);
- 5) species having  $R^1R^2-N-X$  as 3,4-dihydro-1H-isoquinolin-2yl-methyl (e.g., the 36<sup>th</sup> species in claim 60);

6) species having  $R^1R^2-N-X$  as 4-azetidin-1-ylmethyl (e.g., the 39<sup>rd</sup> species in claim 60);

The species are independent or distinct because of the group represented by  $R^1R^2-N-X$ .

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a group and a species to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tamthom N. Truong whose telephone number is 571-272-0676. The examiner can normally be reached on M, T and Th (9:00-5:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



**Tamthom N. Truong**  
Examiner  
Art Unit 1624

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4-23-07



**EMILY BERNHARDT**  
**PRIMARY EXAMINER**  
**GROUP 1600**